Briefing Paper
Biotech MCAN J-15-0013, 0014, 0015, 0016, 0017, 0018

PART I: BACKGROUND DATA

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Dispo Meeting Date: June 18, 2015

A. CBI Claims: Submitter Identity, Chemical identity, Use, Recipient microorganism, Donor microorganism, Genetic construct, Exposure, Production volume, Process information.

B. Submitter: [redacted]

C. **Chemical Identity**: [redacted]

Recipient Microorganism: [redacted]

Donor microorganism: [redacted]

D. Production volume
i) Maximum PV (Year 3): [redacted]

E. Use: [redacted]

PART II: Introduction

The Agency has received a Microbial Commercial Activity Notice from [redacted]. for six intergeneric strains of [redacted]. As per the submitter, the purpose of the genetic modifications is for the [redacted]

PART III: Recommendation and Rationale

Drop from further review.

There is low risk to human health and the environment associated with the production of the six intergeneric strains [redacted]. The genetic modifications done to [redacted] does not pose concerns.

PART IV: Risk Summary

A. Human Health Hazard

The potential health hazards of the recipient microorganism, [redacted], have been evaluated by Ward (2015) [redacted] The recipient microorganism does not pose pathogenicity or toxicity concerns based on the 5(h)(4) risk assessment.

The submission microorganism and the introduced genetic material do not pose pathogenicity or toxicity concerns. There is a low concern for potential allergy from exposure to the submission microorganism. There is no concern for the use of antibiotic resistance genes since the [redacted] used during construction of the submission microorganism were not introduced into the final submission microorganisms.

B. Ecological Hazards

There are low ecological hazard concerns for the recipient microorganism, [redacted] (Muneer, 2015). This [redacted] is ubiquitous in the environment with no known adverse effects to animals or plants or the environment. The genetic modifications done on the recipient microorganism to arrive at the production strain do not pose ecological concerns. Many organisms including animals, plants, and microorganisms produce [redacted] The inserted genetic material does not pose ecological hazards. It merely enables [redacted]

The production strain may be expected to survive in the environment if inadvertently released from [redacted] facilities, however, its potential survival does not pose concerns.